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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,946	08/18/2003	James W. Ryan	JR-14000-CON	4300

7590 04/21/2006

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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/642,946	RYAN, JAMES W.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1-29-04*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-26 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 6, 8, 10, 11, 14-16, drawn to nucleic acid compositions and methods, classified in class 536, subclass 23.1.

II. Claim 7, drawn to a method of producing antibodies, classified in class 530, subclass 387.1.

III. Claims 9, 12, 13, 23, 24, drawn to methods of modulation comprising administration of nucleic acids, classified in class 514, subclass 44.

IV. Claim 25, drawn to a method of identifying genomic variants, classified in class 435, subclass 6.

V. Claim 26, drawn to methods of detecting non-coding nucleic acid sequence specific regions, classified in class 435, subclass 6.

Applicants are additionally required to elect the following with the corresponding elected group:

i. a single nucleic acid construct, or single target gene from claims 1, 23, 24;

ii. a single polypeptide from claims 6, 7;

iii. a single target region from claims 8, 26; and

iv. a single sequence (SEQ. ID No.) from claim 25.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the DNA constructs of Group I can be used for generating recombinant polypeptides in vitro, for primers, cellular localization studies, or as probes for in situ hybridization studies.

Inventions II-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different methods that result in different biological properties, functions or products: methods producing antibodies (Group II); methods of modulation and treatment comprising administration of nucleic acid constructs (Group III); methods of identifying genomic variants (Group IV); and methods of analyzing coding and non-coding regions within a nucleic acid sequence (Group V). Each method involves either monitoring for a distinct function or biological effect, or involves different and distinct methods steps (e.g. comprising administration or use of different and distinct polypeptide or nucleic acid compositions) and therefore each Group comprises different assay or active steps, each examining a different biological outcome. In

addition, the transformation of the different and distinct nucleic acid compositions comprises different and distinct methods steps. The searches required for proper examination of each distinct group are not coextensive, although some searches may be overlapping.

Inventions of Groups I and II-V are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The compositions and steps used in one Group's methods are not required or used in another Group's methods. The compositions of Groups I could be used for other methods, including for the generation of recombinant polypeptides, cellular expression studies or competitive binding assays. For these reasons, the inventions of these different and distinct Groups are capable of supporting separate patents.

The different inventions drawn to nucleic acids, antibodies, or using different polypeptides are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the oligonucleotides and methods comprising them are biologically, structurally and functionally different and distinct from each other. The methods involving the use of a these patentably distinct compositions each utilize a different and distinct composition,

and so utilize distinct methods steps from each other. For these reasons, the inventions of these different Groups are patentably distinct.

Furthermore, searching the inventions of Groups comprising all of these different molecules, and the methods comprising them together would impose a serious search burden. In the instant case, the search of the distinct methods and compositions are not coextensive. There is a search burden also in the non-patent literature. Prior to the concomitant construction and utilization of the different compositions of interest there may be journal articles devoted solely to one Group that would not have described the compositions and methods of the other Group. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of the different Groups together.

The different inventions drawn to each target gene, polynucleotide SEQ ID NO., or polypeptide for generating antibodies are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different compositions and methods comprising them are biologically, structurally and functionally different and distinct from each other. The methods involving the use of a distinct oligonucleotide utilize a different and distinct composition, and so utilizes distinct methods steps from each other. For these reasons, the inventions of these different Groups are patentably distinct.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or

different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods comprising administration of different nucleic acid oligonucleotides are unrelated as they comprise distinct steps and utilize different nucleic acid constructs which demonstrates that each method has a different mode of operation. The methodology and materials necessary for each of these distinct methods differ significantly, and each Group constitutes a biologically, chemically and functionally distinct and different composition and method and therefore each involves a patentably distinct invention. Therefore, each method is divergent in materials and steps. For these reasons the inventions of these different Groups are patentably distinct.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the different oligonucleotides, polypeptides, target regions and target genes and their corresponding SEQ ID Nos. listed in claims 1, 6-8, 23-26, and encompassed by claims 1-26 are subject to restriction. In the instant case, one independent and distinct oligonucleotide sequence, target region, target gene or polypeptide used to generate an antibody will be examined in a single application without restriction. Those sequences or structures which are patentably indistinct from the sequence or region selected by the applicant will also be examined.

Claims 1-26 specifically embrace different oligonucleotides with different SEQ ID Nos. Each of these oligonucleotides is considered to be structurally independent, because each is represented by a unique nucleotide sequence. Furthermore, a search of all the sequences claimed presents an undue burden on the Patent and Trademark

Office to search and examine. In view of the foregoing, applicants are required to elect up to 1 oligonucleotide (SEQ ID No.) and corresponding target sequence.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone number for the Group is **571-273-8300**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO

DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
4-18-06

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PRIMARY EXAMINER